Title

Antegrade common femoral artery closure device use is associated with decreased complications.

Journal

Journal of vascular surgery, 72(5)

ISSN

0741-5214

Authors

Ramirez, Joel L
Zarkowsky, Devin S
Sorrentino, Thomas A
et al.

Publication Date

2020-11-01

DOI

10.1016/j.jvs.2020.01.052

Peer reviewed

From the Western Vascular Society

Antegrade common femoral artery closure device use is associated with decreased complications

Joel L. Ramirez, MD,[a] Devin S. Zarkowsky, MD,[b] Thomas A. Sorrentino, MD,[a] Caitlin W. Hicks, MD, MS,[c] Shant M. Vartanian, MD,[a] Warren J. Gasper, MD,[a] Michael S. Conte, MD,[a] *and* James C. Iannuzzi, MD, MPH,[a]
San Francisco, Calif; Aurora, Colo; and Baltimore, Md

ABSTRACT

Objective: Antegrade femoral artery access is often used for ipsilateral infrainguinal peripheral vascular intervention. However, the use of closure devices (CD) for antegrade access (AA) is still considered outside the instructions for use for most devices. We hypothesized that CD use for antegrade femoral access would not be associated with an increased odds of access site complications.

Methods: The Vascular Quality Initiative was queried from 2010 to 2019 for infrainguinal peripheral vascular interventions performed via femoral AA. Patients who had a cutdown or multiple access sites were excluded. Cases were then stratified into whether a CD was used or not. Hierarchical multivariable logistic regressions controlling for hospital-level variation were used to examine the independent association between CD use and access site complications. A sensitivity analysis using coarsened exact matching was performed using factors different between treatment groups to reduce imbalance between the groups.

Results: Overall, 11,562 cases were identified and 5693 (49.2%) used a CD. Patients treated with a CD were less likely to be white (74.1% vs 75.2%), have coronary artery disease (29.7% vs 33.4%), use aspirin (68.7% vs 72.4%), and have heparin reversal with protamine (15.5% vs 25.6%; all $P < .05$). CD patients were more likely to be obese (31.6% vs 27.0%), have an elective operation (82.6% vs 80.1%), ultrasound-guided access (75.5% vs 60.6%), and a larger access sheath (6.0 ± 1.0 F vs 5.5 ± 1.0 F; $P < .05$ for all). CD cases were less likely to develop any access site hematoma (2.55% vs 3.53%; $P < .01$) or a hematoma requiring reintervention (0.63% vs 1.26%; $P < .01$) and had no difference in access site stenosis or occlusion (0.30% vs 0.22%; $P = .47$) compared with no CD. On multivariable analysis, CD cases had significantly decreased odds of developing any access site hematoma (odds ratio, 0.75; 95% confidence interval, 0.59-0.95) and a hematoma requiring intervention (odds ratio, 0.56; 95% confidence interval, 0.38-0.81). A sensitivity analysis after coarsened exact matching confirmed these findings.

Conclusions: In this nationally representative sample, CD use for AA was associated with a lower odds of hematoma in selected patients. Extending the instructions for use indications for CDs to include femoral AA may decrease the incidence of access site complications, patient exposure to reintervention, and costs to the health care system. (J Vasc Surg 2020;■:1-8.)

Keywords: Closure devices; Antegrade access; Femoral access; Access site complications

Although retrograde access (RA) is more commonly used, lower extremity disease may be safely treated with ipsilateral femoral artery antegrade access (AA).[1,2] AA plays an important role in patients with a narrow or heavily calcified aortic bifurcation, prior aortoiliac or aortofemoral bypass, aortic stent graft, bilateral kissing iliac stents with a raised bifurcation, and patients with tortuous iliofemoral anatomy that makes crossing the aortic bifurcation challenging.[3-5] Although femoral AA can be more technically difficult than RA, and certain

From the Division of Vascular and Endovascular Surgery, University of California, San Francisco[a]; the Division of Vascular Surgery and Endovascular Therapy, University of Colorado, Aurora[b]; and the Division of Vascular Surgery and Endovascular Therapy, Johns Hopkins University, Baltimore.[c]

Supported by institutional start-up funds (J.C.I.) with additional student research support from the Society for Vascular Surgery Student Research Fellowship Award and the American Heart Association Student Scholarship (J.L.R.). The content is solely the responsibility of the authors and does not necessarily represent the official views of the Society for Vascular Surgery or American Heart Association. The funding organizations were not involved in the design and conduct of the study, collection, management, analysis, and interpretation of the data, or preparation, review or approval of the manuscript.

Author conflict of interest: none.

Presented at the Thirty-fourth Annual Meeting of the Western Vascular Society, Maui, Hawaii, September 28 to October 1, 2019.

Additional material for this article may be found online at www.jvascsurg.org.

Correspondence: James C. Iannuzzi, MD, MPH, Division of Vascular and Endovascular Surgery, Department of Surgery, University of California, 400 Parnassus Ave, A-581, San Francisco, CA 94143 (e-mail: james.iannuzzi@ucsf.edu).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

Published by Elsevier Inc. on behalf of the Society for Vascular Surgery.

https://doi.org/10.1016/j.jvs.2020.01.052

patient factors such as obesity may preclude the use of AA, AA has been reported to have a similar incidence of access site complications compared with RA.[6,7]

Arterial access closure devices (CD) allow for expedient closure, avoidance of prolonged manual compression, decreased operating room or angiosuite use, and improved patient satisfaction after peripheral vascular intervention (PVI).[8] However, the instructions for use (IFU) for most CDs indicate their use only for femoral RA. An abundance of data exists supporting the use of CDs for femoral artery access; however, these studies do not differentiate between patients with RA vs AA.[8,9] Although prima facie it seems unlikely that CDs would function differently whether access was retrograde or antegrade, this finding has yet to be described in a large cohort.

The objective of this study was to examine the association of CD use in femoral AA with access site complications, including hematoma, stenosis, or occlusion. We hypothesized that CD use would demonstrate no difference in the incidence of access site complications compared with no CD use.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of prospectively collected registry data from the Vascular Quality Initiative
- **Key Findings:** Closure device (CD) use for antegrade femoral artery access in 5693 infrainguinal peripheral vascular interventions was independently associated with a decreased odds for developing any access site hematoma (odds ratio, 0.75) or a hematoma requiring intervention (odds ratio, 0.56), and was not associated with access site stenosis or occlusion compared with no CD.
- **Take Home Message:** The use of CDs for antegrade femoral artery access is safe, efficacious, and associated with a decreased odds of access site hematoma.

METHODS

Prospectively collected data from the 2010 to 2019 Society for Vascular Surgery Vascular Quality Initiative (VQI) infrainguinal PVIs database was retrospectively analyzed. The VQI has been previously described in the literature.[10] Briefly, the VQI is a national quality improvement database that collects patient-level data on commonly performed vascular procedures, including in-hospital and long-term outcomes. Data are entered by participating hospitals and are available to participating institutions after submission and approval of a written data request. All variables used in this study had a missingness of less than 10%. Missing data were grouped with the referent group to create a conservative estimate for all independent variables. These data were deidentified and did not include any protected health information, which is therefore not considered human research, is exempt from institutional review board approval, and does not require informed consent.

All patients undergoing an infrainguinal PVI with femoral AA were included (Fig). Patients who had a femoral artery cutdown, upper extremity access, or access site other than the femoral artery were excluded. Patients with multiple access sites (ie, bilateral femoral or femoral and upper extremity) were excluded as well, owing to the inability to determine the location of the access site complication.

The primary outcomes were periprocedural access site complications, which included the development of an access site hematoma or access site stenosis or occlusion as defined in the VQI. The secondary outcome was periprocedural development of an access site hematoma requiring an intervention, which was defined as transfusion to treat associated blood loss, thrombin injection, or surgical repair.

Demographic variables examined included age, sex, white race, preoperative ambulatory status (independent or with assistance), Medicare/Medicaid as primary insurer, obesity (body mass index $\geq$30 kg/m^2), current smoking status, coronary artery disease (CAD), hypertension, diabetes mellitus, congestive heart failure, chronic obstructive pulmonary disease, or dialysis (functioning renal transplant or on hemodialysis or peritoneal dialysis), and preoperative medications (angiotensin-converting enzyme inhibitor, aspirin, statin, P2Y$_{12}$ inhibitors, and anticoagulant [warfarin, direct thrombin inhibitors, or factor Xa inhibitors]). Prior operative history included history of coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI), carotid endarterectomy, carotid artery stent, major amputation (below knee or proximal amputation), inflow stent, angioplasty, or bypass, and infrainguinal stent, angioplasty, or bypass. Procedural details that were examined included elective operation, indication for procedure, right-sided access, ultrasound-guided access, largest sheath used, amount of contrast, and heparin reversal with protamine.

There were a total of seven unique CDs registered in this cohort: Perclose (Abbott, Santa Clara, Calif), Starclose (Abbott), Mynx (Cardinal Health, Dublin, Ohio), Angioseal (Terumo, Somerset, NJ), Femoral Introducer Sheath & Hemostasis (Morris Innovative, Bloomington, Ind), ExoSeal Vascular Closure System (Cordis, Santa Clara, Calif), TR Band (Terumo), and other. Consistent with the VQI Society for Vascular Surgery Device Identification Policy, the identities of the individual CDs were blinded, and analysis was constrained to CDs as a whole.

Statistical analysis. All statistical analyses were performed using STATA version 15.0 (StataCorp, College Station, Tex). Cases were then stratified into whether a CD was used or not. Summary statistics were reported using mean and standard deviation for continuous variables,

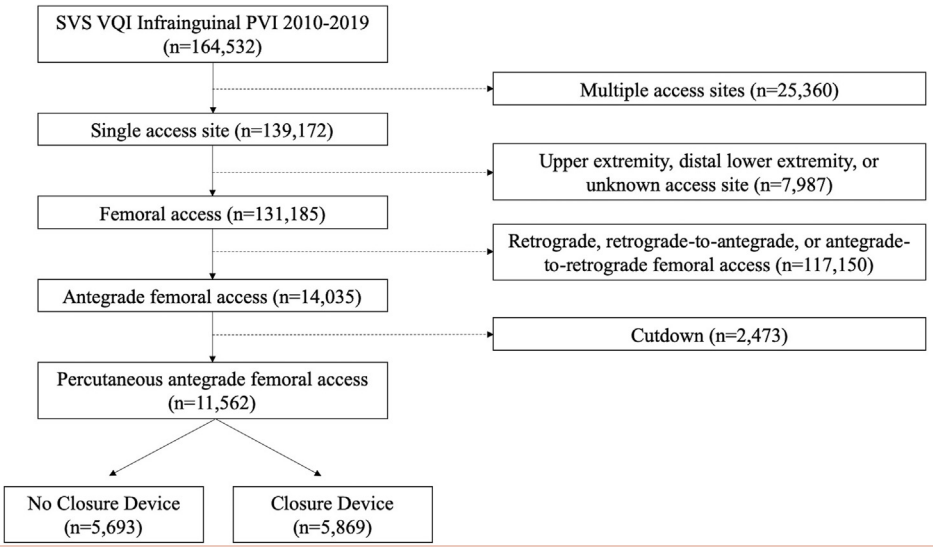

Fig. Cohort inclusion criteria. *PVI,* Peripheral vascular intervention; *SVS,* Society for Vascular Surgery; *VQI,* Vascular Quality Initiative.

along with frequency and percentage for categorical variables. Between group differences were calculated using a χ^2 test for categorical variables and a two-tailed Student *t*-test for continuous variables. Hierarchical multivariable logistic regressions controlling for hospital-level variation were used to examine the independent association between CD use and access site complications. Variables returning a *P* value of less than .10 on univariate analyses progressed to inclusion in the multivariable models. The models were constructed in a stepwise manual method using a *P* value of less than .05 for retention in the models.

To decrease imbalance and bias associated with observational data, the two groups (CD and no CD) were then matched on aspirin use and baseline demographics, comorbidities, operative history, and procedural details that differed on baseline analyses ($P < .05$) using coarsened exact matching (CEM).[11] In brief, CEM organizes variables to discrete values using a binning strategy. Each participant is then assigned a bin signature, which is used to match between groups. CEM reduces imbalance, model dependence, estimation error, researcher bias, and variance between groups. This decrease in imbalance is denoted by the L_1 statistic; imbalance decreases as the L_1 statistic declines. Sensitivity analyses then assessed the association between CDs and the outcomes of interest after CEM.

RESULTS

Overall, 164,532 cases of infrainguinal PVI were identified and 11,562 patients (7.0%) had isolated percutaneous AA (Fig). Of these, a CD was used in 5693 cases (49.2%) (Table I). Patients treated with a CD were less likely to be white (74.1% vs 75.2%), have CAD (29.7% vs 33.4%), use aspirin (68.7% vs 72.4%), and have heparin reversal with protamine (15.5% vs 25.6%; all $P < .05$). CD use was associated with obesity (31.6% vs 27.0%), elective operations (82.6% vs 80.1%), ultrasound-guided access (75.5% vs 60.6%), and a larger access sheath (6.0 ± 1.0 F vs 5.5 ± 1.0 F; $P < .05$ for all; Table II).

CD cases were less likely to develop an access site hematoma (2.55% vs 3.53%; $P = .002$) or a hematoma requiring reintervention (0.63% vs 1.26%; $P = .001$) and had no difference in access site stenosis or occlusion (0.30% vs 0.22%; $P = .467$) compared with no CD (Table III). On multivariable adjusted analysis, patients treated with a CD had significantly decreased odds of developing any access site hematoma (odds ratio [OR], 0.75; 95% confidence interval [CI], 0.59-0.95; Table IV) and a hematoma requiring intervention (OR, 0.56; 95% CI, 0.38-0.81; Table V). Consistent with baseline analyses, there was no significant association between CD and access site stenosis or occlusion on multivariable analysis (Table VI).

Using CEM, the groups were then matched on white race, obesity, CAD, congestive heart failure, aspirin use, elective status, ultrasound guidance, largest sheath size used, heparin reversal with protamine, and prior CABG or PCI, major amputation, inflow stent, angioplasty, or bypass, and infrainguinal stent, angioplasty, or bypass. Prematching imbalance of $L_1 = 0.65$ decreased postmatch to an imbalance of $L_2 = 0.03$, which indicated a decreased imbalance between the groups. After CEM, 5975 total cases were included, and a CD was used in 3273 cases (Supplementary Tables I and II, online only). Although differences between groups were still appreciated among some variables, the degree of differences were smaller than before CEM. Sensitivity analyses after CEM confirmed associations between CD use and any

Table I. Baseline characteristics

Characteristics	CD (n = 5693)	No CD (n = 5869)	*P* value[a]
Demographics			
Age, years			.077
<60	1146 (20.1)	1090 (18.6)	
60-69	1539 (27.0)	1554 (26.5)	
70-79	1635 (28.7)	1724 (29.4)	
≥80	1373 (24.1)	1501 (25.6)	
Female sex	1866 (32.8)	1984 (33.8)	.244
White	4221 (74.1)	4683 (79.8)	**<.001**
Ambulatory	4220 (74.1)	4441 (75.2)	.207
Medicare/Medicaid	3577 (67.9)	3429 (66.4)	.128
Comorbidities			
Obese	1799 (31.6)	1586 (27.0)	**<.001**
Current smoker	1425 (25.0)	1382 (23.6)	.065
CAD	1690 (29.7)	1958 (33.4)	**<.001**
Prior CABG or PCI	1868 (32.8)	2082 (35.5)	**.003**
Prior CEA or CAS	157 (2.8)	147 (2.5)	.416
Hypertension	4981 (87.5)	5190 (88.4)	.123
Diabetes	3330 (58.5)	3385 (57.7)	.376
Congestive heart failure	1226 (21.5)	1398 (23.8)	**.003**
COPD	1205 (21.2)	1228 (20.9)	.749
Dialysis	754 (13.2)	828 (14.0)	.233
Preoperative medications			
ACE inhibitor	2573 (45.2)	2466 (42.0)	**.001**
Aspirin	3908 (68.7)	4251 (72.4)	**<.001**
Anticoagulant	97 (1.7)	94 (1.6)	.715
$P2Y_{12}$ inhibitor	2432 (42.7)	2438 (41.5)	.200
Statin	3789 (66.6)	4044 (68.9)	**.007**

ACE, Angiotensin-converting enzyme; *CABG*, coronary artery bypass graft; *CAD*, coronary artery disease; *CAS*, carotid artery stent; *CD*, closure device; *CEA*, carotid endarterectomy, *COPD*, chronic obstructive pulmonary disease; *PCI*, percutaneous coronary intervention.
Values are number (%). Boldface entries indicate statistical significance.
[a]Calculated using a χ^2 test for categorical variables and a Student *t*-test for continuous variables.

access site hematoma (OR, 0.74; 95% CI, 0.54-1.00) and access site hematoma requiring intervention (OR, 0.54; 95% CI, 0.29-0.99; Table VII).

DISCUSSION

In this nationally representative surgical quality improvement database, CD use for femoral AA was associated with lower odds of any access site hematoma and hematoma requiring intervention when compared with no CD use. Although the overall incidence of access site stenosis or occlusion was generally low (0.26%), the use of a CD was not associated with an increased odds for stenosis or occlusion. These results collectively suggest that CDs may be safely used for femoral AA and may improve access site outcomes and the incidence of complications in selected cases.

On baseline analyses, patients who were treated with a CD had a higher proportion of obesity, which has previously been reported to independently predict access site complications in patients undergoing antegrade PVI, even when a CD was used.[12] The burden of overall atherosclerotic disease was lower in the CD group compared with the no CD group, as indicated by a lower proportion of patients with a history of CAD, CABG, PCI, major amputation, and previous inflow or infrainguinal stent, angioplasty, or bypass. Patients receiving an intervention owing to occlusive disease were also less likely to be treated with a CD. This finding likely represents a hesitancy to use a CD in atherosclerotic or stenosed vessels, because deployment is anecdotally more challenging. Reports suggest that CDs have similar efficacy and rates of complications in patients with peripheral artery disease or calcified plaque.[13-16] CDs had a lower proportion of patients treated with aspirin, which may be protective against postoperative hematoma, but they also had a 10% lower rate of heparin reversal with protamine.

Patients treated with a CD had a larger mean sheath size, which has been reported to be independently

Table II. Procedural details

Characteristics	CD (n = 5693)	No CD (n = 5869)	*P* value[a]
Operative history			
Prior major amputation (ipsilateral or contralateral)	870 (15.3)	1118 (19.1)	**<.001**
Prior inflow stent or angioplasty			**<.001**
None	4989 (87.6)	4990 (85.0)	
Ipsilateral	222 (3.9)	247 (4.2)	
Contralateral	177 (3.1)	216 (3.7)	
Bilateral	305 (5.4)	416 (7.1)	
Prior inflow bypass			**<.001**
None	5429 (95.4)	5483 (93.4)	
Ipsilateral	74 (1.3)	81 (1.4)	
Contralateral	52 (0.9)	58 (1.0)	
Bilateral	138 (2.4)	247 (4.2)	
Prior infrainguinal stent or angioplasty			**.001**
None	3436 (60.4)	3338 (56.9)	
Ipsilateral	1067 (18.7)	1237 (21.1)	
Contralateral	657 (11.5)	698 (11.9)	
Bilateral	533 (9.4)	596 (10.2)	
Prior infrainguinal bypass			**<.001**
None	5088 (89.4)	4918 (83.8)	
Ipsilateral	228 (4.0)	335 (5.7)	
Contralateral	284 (5.0)	435 (7.4)	
Bilateral	93 (1.6)	181 (3.1)	
Procedural details			
Elective	4703 (82.6)	4703 (80.1)	**.001**
Indication			**<.001**
Occlusive disease	5105 (89.7)	5509 (93.9)	
Aneurysm	231 (4.1)	105 (1.8)	
Occlusive or aneurysm	40 (0.7)	24 (0.4)	
None/unknown	317 (5.6)	231 (3.9)	
Right-sided access	3105 (54.5)	3168 (54.0)	.550
Ultrasound guidance	4299 (75.5)	3556 (60.6)	**<.001**
Largest sheath size, F	6.0 ± 1.0	5.5 ± 1.0	**<.001**
Contrast, mL	76.6 ± 51.4	77.6 ± 53.3	.317
Protamine	883 (15.5)	1505 (25.6)	**<.001**

CD, Closure device.
Values are mean ± standard deviation or number (%). Boldface entries indicate statistical significance.
[a]Calculated using a χ^2 test for categorical variables and a Student *t*-test for continuous variables.

associated with access site complications after femoral RA and AA.[17,18] Patients treated with a CD were also 15% more likely to have had ultrasound-guided access, which has been reported to be protective from access site complications.[19,20] After CEM, differences in baseline characteristics, including a history of previous inflow or infrainguinal stent, angioplasty, or bypass, indication for intervention, ultrasound guidance, largest sheath size, and heparin reversal with protamine were ameliorated and the results of the multivariable models remained largely unchanged.

Cragg et al[21] reported in a prospective study of 556 patients undergoing femoropopliteal angioplasty that compared with femoral RA, AA did not have a significantly higher rate of access site complications (AA, 3.7% vs RA, 1.1%; $P = .186$), which were defined as retroperitoneal hematoma, pseudoaneurysm, hematoma requiring transfusion, arteriovenous fistula formation, acute thrombosis, and need for surgical repair. Although not statistically significant, Cragg et al[21] also reported fewer access site complications in patients treated with CDs. Siracuse et al[7] also reported no difference in access site

Table III. Access site complications

Access site complications	CD (n = 5693)	No CD (n = 5869)	*P* value[a]
Hematoma			**.004**
No	5548 (97.5)	5662 (96.5)	
Minor	109 (1.91)	133 (2.27)	
Transfusion	20 (0.35)	39 (0.66)	
Thrombin injection	3 (0.05)	12 (0.20)	
Operative treatment	13 (0.23)	23 (0.39)	
Any hematoma	145 (2.55)	207 (3.53)	**.002**
Hematoma requiring intervention	36 (0.63)	74 (1.26)	**.001**
Access site stenosis or occlusion	17 (0.30)	13 (0.22)	.467

CD, Closure device.
Values are number (%). Boldface entries indicate statistical significance.
[a]Calculated using a χ^2 test.

Table IV. Multivariable analysis of any access site hematoma

Covariates	OR	95% CI	*P* value
CD	0.75	0.59-0.95	**.018**
Age, years: Ref <60			
60-69	0.76	0.50-1.14	.180
70-79	1.48	1.06-2.08	**.022**
>80	1.75	1.24-2.46	**.001**
Female sex	1.50	1.21-1.86	**<.001**
Prior inflow stent or angioplasty: Ref none			
Ipsilateral	1.68	1.12-2.53	**.012**
Contralateral	1.17	0.68-2.02	.571
Bilateral	1.35	0.94-1.96	.105
Prior infrainguinal bypass: Ref none			
Ipsilateral	1.47	0.96-2.24	.074
Contralateral	1.64	1.12-2.42	**.012**
Bilateral	1.02	0.46-2.25	.959
Contrast, mL	1.002	1.000-1.005	**.027**
Elective	0.75	0.59-0.96	**.022**
Diabetes	0.70	0.55-0.88	**.003**
Prior major amputation (ipsilateral or contralateral)	0.70	0.51-0.96	**.027**

CD, Closure device; *CI,* confidence interval; *OR,* odds ratio.
Boldface entries indicate statistical significance.

complications, including hematoma, between femoral RA and AA, although this study did not report on the use of CDs.

Owing to the VQI device identification policy, the identities of the individual devices were unable to be determined in the current study. However, previous reports support the feasibility and safety of the use of a wide range of CDs for femoral AA.[22] Duda et al[23] examined the use of suture-mediated CDs, Techstar and Prostar Plus devices (Abbott) in 80 patients undergoing femoropopliteal angioplasty and reported an access site hematoma rate of 5%.[23] Collagen- and polyethylene glycol plug-mediated CDs have also been reported to perform adequately in femoral AA. In 2374 diabetic patients with critical limb ischemia, the use of the Angio-Seal CD for femoral AA was associated with the lowest rate of major access-site complications (20/1889 [1.1%]) compared with RA Angio-Seal use (5/278 [1.8%]) and manual compression (4/205 [2.0%]).[24] Pruski et al[25] reported a 95% (63/66) procedure success rate and no major access site complications after using the Mynx CD for femoral AA for PVI. However, it is important to note that the Angio-Seal device is the only CD that includes use for AA in the IFU.

The ExoSeal Vascular Closure System is the most studied CD for femoral AA, although the studies are limited by small sample sizes. Boschewitz et al[26] reported a 98% (145/148) technical success using the ExoSeal, no major access site complications, and a single occurrence of an access site hematoma of less than 3 cm (1/148 [0.7%]). However, there was a significant association ($P < .05$) between preoperative aspirin, clopidogrel, and abciximab use with requiring additional manual compression for hemostasis.[26] In the current study, no preoperative medications were associated with access site hematoma and were therefore not included in the multivariable models. In two other studies using the ExoSeal CD for femoral AA, rates of postoperative hematoma were 3.4% (2/59) and 5.4% (9/168).[27,28] Similar to the previously mentioned studies, the use of the Starclose CD has also been reported to be safe and efficacious in femoral AA, which was demonstrated in 30 patients with critical limb ischemia who underwent peripheral angioplasty.[29]

The data reported in this study suggest that CDs decrease hematoma formation without increasing vessel stenosis when deployed for femoral AA closure, which is consistent with the results reported in other studies. However, this is the largest and most nationally representative sample size studied to date. Using CDs for femoral AA may decrease access site complications and operating room use.

Limitations. This study has limitations. Although data in the VQI are collected prospectively, this was a retrospective review of a large database. Although the VQI collects data on the development of access site arteriovenous fistula and pseudoaneurysms, these variables were very poorly reported with a missing rate of more than 60%. This study therefore cannot make any meaningful conclusions on the effect of CDs on access site arteriovenous fistula or pseudoaneurysm. The VQI does collect data on failed CD deployment attempts but the variable had only started to be recorded in

Table V. Multivariable analysis of access site hematoma requiring intervention

Covariates	OR	95% CI	*P* value
CD	0.56	0.38-0.81	**.002**
Age, years: Ref <60			
60-69	0.96	0.44-2.08	.918
70-79	2.46	1.31-4.61	**.005**
>80	2.67	1.36-5.22	**.004**
Prior infrainguinal bypass: Ref none			
Ipsilateral	1.94	0.96-3.90	.063
Contralateral	1.87	1.04-3.35	**.037**
Bilateral	2.48	1.11-5.50	**.026**
Female sex	1.99	1.34-2.97	**.001**
Congestive heart failure	1.72	1.11-2.68	**.016**
Elective	0.56	0.35-0.89	**.015**

CD, Closure device; *CI,* confidence interval; *OR,* odds ratio.
Boldface entries indicate statistical significance.

Table VI. Multivariable analysis of access site stenosis or occlusion

Covariates	OR	95% CI	*P* value
CD	1.43	0.60-3.39	.414
Prior CABG or PCI	2.65	1.35-5.21	**.005**
Elective	0.32	0.14-0.72	**.006**

CABG, Coronary artery bypass graft; *CI,* confidence interval; *OR,* odds ratio; *PCI,* percutaneous coronary intervention.
Boldface entries indicate statistical significance.

2015 and is very poorly reported (<50%) in the years that it was collected and was therefore not included in this study. Therefore, we cannot accurately determine the rate of CD deployment failure. However, because patients with femoral artery cutdowns were excluded from this study, that would include patients who had failed CD deployment and required a cutdown to salvage. Owing to the way the VQI PVI data are organized, this study did not include patients with multiple access sites (ie, bilateral femoral or femoral and upper extremity). Owing to the VQI device identification policy, the identities of the individual CDs were unable to be determined and analyses were only able to be completed using an aggregate CD variable. It is possible that only certain CDs, or that certain forms of CDs (ie, suture mediated or collagen mediated), may confer a lesser odds of access site hematoma. Although, owing to the low incidence of access site complications, even if CD identities were known, analyses of individual devices would likely be limited by low power. Further study of these individual devices will be required before making formal changes to the IFU.

Table VII. Multivariable analysis of access complications with matched data comparing the use of closure devices (CD)[a]

Complication	OR	95% CI	*P* value
Any hematoma[b]	0.74	0.54-1.00	.053
Hematoma requiring intervention[c]	0.54	0.29-0.99	**.047**
Stenosis or occlusion[d]	0.97	0.28-3.42	.963

CABG, Coronary artery bypass graft; *CI,* confidence interval; *CHF,* congestive heart failure; *OR,* odds ratio; *PCI,* percutaneous coronary intervention.
Boldface entries indicate statistical significance.
[a]Matched for white race, obesity, coronary artery disease, CHF, aspirin use, elective procedure, ultrasound guidance, largest sheath size used, heparin reversal with protamine, and prior CABG or PCI, major amputation, inflow stent or angioplasty, inflow bypass, infrainguinal stent or angioplasty, and infrainguinal bypass.
[b]Adjusted for age, sex, elective operation, volume of contrast used, history of diabetes, prior major amputation, prior inflow stent or angioplasty, and prior infrainguinal bypass.
[c]Adjusted for age, sex, elective operation, CHF, and prior infrainguinal bypass.
[d]Adjusted for elective operation and history of CABG or PCI.

Analyses of access site stenosis or occlusion are likely underpowered as the incidence of complication was low (only 30 total recorded cases). Access site stenosis or occlusion may also be underreported since it may not present acutely or be initially symptomatic and would therefore not be recorded in the VQI. Last, because the VQI does not collect long-term follow-up data on access site complications, all of the data presented in this study represents periprocedural outcomes and conclusions cannot be made regarding the long-term impact of CDs.

CONCLUSIONS

In this nationally representative sample, the use of CDs for AA was associated with a lower odds of postoperative hematoma and hematoma requiring reintervention. CDs for AA may improve access site outcomes with a commensurate increase in patient satisfaction and cost savings to the health care system.

AUTHOR CONTRIBUTIONS

Conception and design: JR, DZ, JI
Analysis and interpretation: JR, DZ, TS, CH, SV, WG, MC, JI
Data collection: JR, DZ, JI
Writing the article: JR, DZ, JI
Critical revision of the article: JR, DZ, TS, CH, SV, WG, MC, JI
Final approval of the article: JR, DZ, TS, CH, SV, WG, MC, JI
Statistical analysis: JR, DZ, JI
Obtained funding: JR, JI
Overall responsibility: JI

REFERENCES

1. Bosiers M, Deloose K, Callaert J. Anterograde or retrograde arterial access for diabetic limb revascularization. Semin Vasc Surg 2018;31:76-80.

2. Smialkowski AO, Huilgol RL. Percutaneous endovascular repair of popliteal artery aneurysms. Ann Vasc Surg 2014;28:1469-72.
3. Grenon SM, Reilly LM, Ramaiah VG. Technical endovascular highlights for crossing the difficult aortic bifurcation. J Vasc Surg 2011;54:893-6.
4. Narins CR. Access strategies for peripheral arterial intervention. Cardiol J 2009;16:88-97.
5. Li Y, Esmail A, Donas KP, Pitoulias G, Torsello G, Bisdas T, et al. Antegrade vs crossover femoral artery access in the endovascular treatment of isolated below-the-knee lesions in patients with critical limb ischemia. J Endovasc Ther 2017;24:331-6.
6. Nice C, Timmons G, Bartholemew P, Uberoi R. Retrograde vs. antegrade puncture for infra-inguinal angioplasty. Cardiovasc Intervent Radiol 2003;26:370-4.
7. Siracuse JJ, Farber A, Cheng TW, Raulli SJ, Jones DW, Kalish JA, et al. Common femoral artery antegrade and retrograde approaches have similar access site complications. J Vasc Surg 2019;69:1160-6.e2.
8. Noori VJ, Eldrup-Jorgensen J. A systematic review of vascular closure devices for femoral artery puncture sites. J Vasc Surg 2018;68:887-99.
9. Robertson L, Andras A, Colgan F, Jackson R. Vascular closure devices for femoral arterial puncture site haemostasis. Cochrane Database Syst Rev 2016;3:CD009541.
10. Cronenwett JL, Kraiss LW, Cambria RP. The Society for Vascular Surgery Vascular Quality Initiative. J Vasc Surg 2012;55:1529-37.
11. Iacus SM, King G, Porro G. Causal Inference Without balance checking: coarsened exact matching. Political Analysis 2012;20:1-24.
12. Minko P, Katoh M, Graber S, Buecker A. Obesity: an independent risk factor for insufficient hemostasis using the AngioSeal vascular closure device after antegrade puncture. Cardiovasc Intervent Radiol 2012;35:775-8.
13. Kara K, Mahabadi AA, Berg MH, Kahlert P, Longwitz D, Erbel R, et al. Utilization of collagen-based vascular closure devices in patients with severe peripheral artery disease. J Invasive Cardiol 2013;25:19-22.
14. Kara K, Kahlert P, Mahabadi AA, Plicht B, Lind AY, Longwitz D, et al. Comparison of collagen-based vascular closure devices in patients with vs. without severe peripheral artery disease. J Endovasc Ther 2014;21:79-84.
15. Starnes BW, O'Donnell SD, Gillespie DL, Goff JM, Rosa P, Parker MV, et al. Percutaneous arterial closure in peripheral vascular disease: a prospective randomized evaluation of the Perclose device. J Vasc Surg 2003;38:263-71.
16. Mackrell PJ, Kalbaugh CA, Langan EM 3rd, Taylor SM, Sullivan TM, Gray BH, et al. Can the Perclose suture-mediated closure system be used safely in patients undergoing diagnostic and therapeutic angiography to treat chronic lower extremity ischemia? J Vasc Surg 2003;38:1305-8.
17. Levin SR, Farber A, Bertges DJ, Ferris M, Cheng TW, Arinze N, et al. Larger sheath size for infrainguinal endovascular intervention is associated with minor but not major morbidity or mortality. Ann Vasc Surg 2019;60:327-34.
18. Wheatley BJ, Mansour MA, Grossman PM, Munir K, Cali RF, Gorsuch JM, et al. Complication rates for percutaneous lower extremity arterial antegrade access. Arch Surg 2011;146:432-5.
19. Lo RC, Fokkema MT, Curran T, Darling J, Hamdan AD, Wyers M, et al. Routine use of ultrasound-guided access reduces access site-related complications after lower extremity percutaneous revascularization. J Vasc Surg 2015;61:405-12.
20. Sobolev M, Slovut DP, Lee Chang A, Shiloh AL, Eisen LA. Ultrasound-guided catheterization of the femoral artery: a systematic review and meta-analysis of randomized controlled trials. J Invasive Cardiol 2015;27:318-23.
21. Cragg J, Lowry D, Hopkins J, Parker D, Kay M, Duddy M, et al. Safety and outcomes of ipsilateral antegrade angioplasty for femoropopliteal disease. Vasc Endovascular Surg 2018;52:93-7.
22. Gutzeit A, van Schie B, Schoch E, Hergan K, Graf N, Binkert CA. Feasibility and safety of vascular closure devices in an antegrade approach to either the common femoral artery or the superficial femoral artery. Cardiovasc Intervent Radiol 2012;35:1036-40.
23. Duda SH, Wiskirchen J, Erb M, Schott U, Khaligi K, Pereira PL, et al. Suture-mediated percutaneous closure of antegrade femoral arterial access sites in patients who have received full anticoagulation therapy. Radiology 1999;210:47-52.
24. Lupattelli T, Tannouri F, Garaci FG, Papa G, Pangos M, Somalvico F, et al. Efficacy and safety of antegrade common femoral artery access closure using the AngioSeal device: experience with 1889 interventions for critical limb ischemia in diabetic patients. J Endovasc Ther 2010;17:366-75.
25. Pruski MJ Jr, Blachut AM, Konkolewska M, Janas A, Hrycek E, Buszman PP, et al. MynxGrip for closure of antegrade puncture after peripheral interventions with same-day discharge. Vasc Endovascular Surg 2017;51:67-71.
26. Boschewitz JM, Pieper CC, Andersson M, Nadal J, Schild HH, Meyer C. Efficacy and time-to-hemostasis of antegrade femoral access closure using the ExoSeal vascular closure device: a retrospective single-center study. Eur J Vasc Endovasc Surg 2014;48:585-91.
27. Maxien D, Behrends B, Eberhardt KM, Saam T, Thieme SF, Reiser MF, et al. Evaluation of the 6-F ExoSeal vascular closure device in antegrade femoral artery punctures. J Endovasc Ther 2012;19:836-43.
28. Hackl G, Gary T, Belaj K, Hafner F, Rief P, Deutschmann H, et al. Exoseal for puncture site closure after antegrade procedures in peripheral arterial disease patients. Diagn Interv Radiol 2014;20:426-31.
29. Fantoni C, Medda M, Mollichelli N, Neagu A, Briganti S, Lo Monaco F, et al. Clip-based arterial haemostasis after antegrade common femoral artery puncture. Int J Cardiol 2008;128:427-9.

Submitted Nov 3, 2019; accepted Jan 15, 2020.

Additional material for this article may be found online at www.jvascsurg.org.

Supplementary Table I (online only). Baseline characteristics after matching

Characteristics	CD (n = 3273)	No CD (n = 2702)	*P* value[a]
Demographics			
Age, years			.543
<60	639 (19.5)	495 (18.3)	
60-69	834 (25.5)	699 (25.9)	
70-79	926 (28.3)	753 (27.9)	
>80	874 (26.7)	755 (27.9)	
Female sex	1126 (34.4)	963 (35.6)	.318
White	2539 (77.6)	2222 (82.2)	**<.001**
Ambulatory	2540 (77.6)	2158 (79.9)	**.034**
Medicare/Medicaid	2031 (66.5)	1578 (65.5)	.424
Comorbidities			
Obese	867 (26.5)	650 (24.1)	**.031**
Current smoker	830 (25.4)	649 (24.0)	.232
CAD	767 (23.4)	711 (26.3)	**.010**
Prior CABG or PCI	898 (27.4)	809 (29.9)	**.033**
Prior CEA or CAS	85 (2.6)	63 (2.3)	.511
Hypertension	2795 (85.4)	2345 (86.8)	.122
Diabetes	1855 (56.7)	1468 (54.3)	.069
Congestive heart failure	487 (14.9)	419 (15.5)	.501
COPD	584 (17.8)	525 (19.4)	.116
Dialysis	379 (11.6)	329 (12.2)	.478
Preoperative medications			
ACE inhibitor	1505 (46.0)	1150 (42.6)	**.008**
Aspirin	2327 (71.1)	2022 (74.8)	**.001**
Anticoagulant	44 (1.3)	33 (1.2)	.675
$P2Y_{12}$ inhibitor	1257 (38.4)	986 (36.5)	.128
Statin	2083 (63.6)	1769 (65.5)	.142

ACE, Angiotensin-converting enzyme; *CABG*, coronary artery bypass graft; *CAD*, coronary artery disease; *CAS*, carotid artery stent; *CEA*, carotid endarterectomy; *CD*, closure device; *COPD*, chronic obstructive pulmonary disease; *PCI*, percutaneous coronary intervention.
Values are number (%). Boldface entries indicate statistical significance.
[a]Calculated using a χ^2 test for categorical variables and a Student's *t*-test for continuous variables.

Supplementary Table II (online only). Procedural details after matching

Characteristics	CD (n = 3273)	No CD (n = 2702)	*P* value[a]
Operative history			
Prior major amputation (ipsilateral or contralateral)	258 (7.9)	214 (7.9)	.957
Prior inflow stent or angioplasty			**.003**
None	3158 (96.5)	2564 (94.9)	
Ipsilateral	29 (0.9)	21 (0.8)	
Contralateral	25 (0.8)	28 (1.0)	
Bilateral	61 (1.9)	89 (3.3)	
Prior inflow bypass			.560
None	3244 (99.1)	2668 (98.7)	
Ipsilateral	3 (0.1)	3 (0.1)	
Contralateral	3 (0.1)	3 (0.1)	
Bilateral	23 (0.7)	28 (1.0)	
Prior infrainguinal stent or angioplasty			.769
None	2285 (69.8)	1903 (70.4)	
Ipsilateral	552 (16.9)	429 (15.9)	
Contralateral	257 (7.9)	220 (8.1)	
Bilateral	179 (5.5)	150 (5.6)	
Prior infrainguinal bypass			.892
None	3179 (97.1)	2616 (96.8)	
Ipsilateral	44 (1.3)	38 (1.4)	
Contralateral	46 (1.4)	44 (1.6)	
Bilateral	4 (0.1)	4 (0.2)	
Procedural details			
Elective	2870 (87.7)	2354 (87.1)	.511
Indication			.158
Occlusive disease	3021 (92.3)	2527 (93.5)	
Aneurysm	63 (1.9)	39 (1.4)	
Occlusive or aneurysm	8 (0.2)	10 (0.4)	
None/unknown	181 (5.5)	126 (4.7)	
Right-sided access	1820 (55.6)	1484 (54.9)	.597
Ultrasound guidance	2536 (77.5)	1791 (66.3)	**<.001**
Largest sheath size, F	5.8 ± 0.6	5.6 ± 0.7	**<.001**
Contrast, mL	77.0 ± 50.9	82.3 ± 55.9	**<.001**
Protamine	389 (11.9)	462 (17.1)	**<.001**

CD, Closure device.
Values are mean ± standard deviation or number (%). Boldface entries indicate statistical significance.
[a]Calculated using a χ^2 test for categorical variables and a Student *t*-test for continuous variables.